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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/501,401

07/15/2004

Hisanori Kachi

1232-31

2796

23117

7590

03/17/2008

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/501,401      | <b>Applicant(s)</b><br>KACHI ET AL. |  |
|                              | <b>Examiner</b><br>Eric E. Silverman, PhD | <b>Art Unit</b><br>1618             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-15-04, 10-12-04, 11-28-2007</u> .                           | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

The preliminary amendment, 7/15/2004, is acknowledged. Claims 1 - 7 are pending in this action.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 14 of copending Application No. 10/575,260 in view of EP 1044672. Although the conflicting claims are not identical, they are not patentably distinct from each other because while copending claim 1 does not require an inorganic salt, this is required by copending

claim 8. Further, while the copending claims do not specifically recite W/O emulsion, they have all of the same ingredients as instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the percent of particular ingredients by mass “based on the total mass of the water-soluble inorganic salt and water.” It is unclear how the compounds other than the inorganic salt and water can have their mass percent based on the content of the inorganic salt and water only.

Claim 7 recites the preparation of claim 1, wherein “at least one of physical properties, etc.-improving agents generally used in preparations for external use on the skin is compounded.” This appears to be an unacceptable translation from another language. It is unclear what is encompassed by “etc.” and unclear what “improving agents generally used in preparations for external use on the skin” are. It is also unclear what is meant by “compounded”. For the purposes of compact prosecution, the claim is being interpreted to mean that at least one additional excipient, acceptable for

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application to skin, is included in the composition. A clarifying amendment would be helpful.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-273433, of record ("433" or "the 433 reference") in view of EP 1044672 ("672" or "the 672 reference") of record.

Note that in the 433 reference, the USPTO has furnished its own translation of Tables 2, 3, and 4. The USPTO translation is cited on a PTO 892.

The 433 reference teaches compositions having an ester compound made from the esterification of glycerin, behenic acid, and eicosan dicarboxylic acid, as required by instant claims 1 and 6 (table 2, paragraph 0016). The compositions are oil-in-water emulsions (paragraph 0010), and are used as sunscreens (paragraphs 0007 and 0008, describing the compositions as having “ultraviolet ray absorbent is offered”). The ratio of the glyceryl, behenic acid, and eicosane diacid is commensurate with that required by instant claim 2 (paragraph 0025). The formulation, as expounded in table 2 (see USPTO translation of this table), includes octyl methoxycinnamate (an ester oil), liquid paraffin and squalane (oils other than ester oil) and PEG 6000 (a surfactant). Other excipients, such as stearates and dibutylene glycol are included, as per instant claim 7. The ratio of ester compound and ester oil is commensurate with instant claim 4. The amount of ester compound is between 0.1 and 20% by weight, which is believed to read on instant claim 3. Note that with respect to claim 3, because the claim is indefinite as discussed above, it is not clear what weight percents are needed to satisfy this claim. The weight percents of the 433 reference, as disclosed and suggested by table 2, meet these limitations as they are best understood.

What is lacking is the inorganic salt.

The 672 reference teaches oil-in-water cosmetics for application to skin or hair (paragraph 0002). Inorganic salts or amino acids are added to impart stability to W/O emulsion (abstract). The inorganic salts are chosen from those listed in claim 5, for example, sodium chloride, potassium chloride, aluminum sulfate, etc.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include inorganic salts, particularly those taught by the 672 reference, in the compositions of the 433 reference. This combination is obvious for at least two reasons.

First, the 433 reference suggest a tangible advantage that could be gained from addition of such salts, namely, that the stability of the emulsion will increase. The artisan would thus find it obvious to add the salts and would expect a more stable emulsion.

Second, the claims represent no more than the combination of elements known in the art, where each element serves its art-recognized, predictable function. The additional agent in 433, the inorganic salts, are recognized as to act as a stabilizer. Based on the disclosure, the inorganic salts appear to serve the same function in the instantly claimed invention; there is no evidence to indicate any unexpected result.

### ***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman, PhD/  
Examiner, Art Unit 1618